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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/148,973	09/04/1998	J.TIMOTHY GREENAMYRE	PC10023A	4263

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07/11/2005

PFIZER INC
235 E 42ND STREET
NEW YORK, NY 10017

EXAMINER

SHIBUYA, MARK LANCE

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/148,973

Applicant(s)

GREENAMYRE ET AL.

Examiner

Mark L. Shibuya

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-7 is/are rejected.
- 7) ☐ Claim(s) 4,8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. Claims 1-8 are pending.

Withdrawn Rejections

2. The rejection of claim 4 under 35 U.S.C. § 112, second paragraph, is withdrawn in view of applicant's amendment to the claim, entered 2/7/2005.

3. The rejection of claims 1-3 and 5-7 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in view of applicant's arguments.

Maintained Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 1-3 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arnold et al. (US 5,670,516), Gerlach (Danish Medical Bulletin, 1979 26/5 pp. 209-

245) and Adams et al. (Principles of Neurology, on PTO-1449). This rejection maintains the reasons of record as set forth in the previous Office action.

Response to Arguments

Applicant argues that because “the Gerlach article supports the Menniti declaration in that it is surprising that AMPA does not potentiate hyperkinetic dyskinesia and that the Gerlach article teaches that L-dopa induced hyperkinesias is only an analogue clinically, but probably not pathogenically, it would not have been obvious to use AMPA receptor antagonists with dopamine agonist therapy. Thus, the 103(a) rejection should be withdrawn.”

Applicant's arguments, filed 2/7/2005, have been fully considered but they are not persuasive. As understood by the examiner, applicant does *not* argue that a *prima facie* case for obvious has not been established, but rather that the claimed invention is drawn to an unexpected result.

Applicant has the burden of establishing results are unexpected and significant. “The evidence relied upon should establish “that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance”. MPEP 716.02(b) (citing *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992).

Applicant still argues, as sound, the reasoning of the Menniti Declaration that because the references of Klogether et al. and Loschmann et al. demonstrated that an AMPA receptor antagonist *potentiates* the effects of a dopamine agonist in animal models of bradykinesia, therefore the claimed invention's limitation that AMPA antagonists *inhibit* dopamine agonist induced dyskinesia was unanticipated and

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contraindicated. Applicant cites p. 209, para 2.0 in the reference of Gerlach, as teaching that there is considerable amount of both clinical and pathogenetic overlap between acute dystonia, parkinsonism and tardive dyskinesia. As understood by the examiner, applicant argues that Gerlach therefore teaches that dopamine agonist-induced dyskinesia (as claimed) is the same as bradykinesia, at least to extent that a similar result would be expected (i.e., potentiation) from the administration of an AMPA receptor antagonist. But, the final sentence of the same para 2.0 at p. 209 (Gerlach reference) goes on to state: "However, the classification mentioned is convenient from a didactic and *therapeutic point of view*, and will therefore be retained in what follows, (emphasis added).

The examiner respectfully submits that, in regard to practical significance, and even if the pathogeneses of acute dystonia, parkinsonism and tardive dyskinesia were not perfectly understood at the time of filing, one of ordinary skill in the art would have looked to the Gerlach reference for the teaching that dopamine agonist-induced dyskinesia to be an obvious clinical analogue to tardive dyskinesia, at least from a therapeutic point of view. And, after all, the claimed method of treating is contemplated as having a therapeutic use.

Applicant's arguments that because Gerlach teaches that L-dopa-induced hyperkinesia is the same as tardive dyskinesia (TD) in the clinical setting, but not necessarily as of the same pathogenesis, and therefore, the claimed invention is surprising, are not persuasive. The examiner respectfully submits, from a practical point of view, that it would have been *prima facie* obvious for the practitioner to treat

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dopamine agonist-induced dyskinesia with an AMPA receptor antagonist, at least in the clinical setting, and even if the pathogeneses of L-dopa-induced hyperkinesia or TD was not fully explicated. Therefore, applicant has not met applicant's burden of establishing results are unexpected and significant.

Conclusion

5. Claims 1-3 and 5-7 stand finally rejected.
6. Claims 4 and 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 573-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BENNETT CELSA
PRIMARY EXAMINER

Mark Shibuya
Examiner
Art Unit 1639

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A large, stylized handwritten signature in black ink, likely belonging to Mark Shibuya, is written over the printed name and title.